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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,995	03/23/2004	Marwan Abboud	21819-194U	2340

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CHRISTOPHER & WEISBERG, P.A.
200 EAST LAS OLAS BOULEVARD
SUITE 2040
FORT LAUDERDALE, FL 33301

EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

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01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,995	ABBOUD ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-11 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/08; 6/2/08; 9/5/08; 9/5/08; 12/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2007 has been entered.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11 and 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose the specific step of inflating an expandable membrane to a predetermined target pressure than exceeding the target pressure during ablation. Further, there is no disclosure of a pressure between 5 and 20 psi. Applicant's disclosure of a range that may include the 5-20 psi range is not a disclosure of the specific range of 5-20 psi.

With specific regards to claim 10, there is no disclosure of the steps being performed in accordance with an RF energy device, particularly with regard to the pressure being used. It is generally known in the art that RF balloon catheters typically employ a higher balloon pressure as the potential rupture of such a balloon has less impact on a body since there is no cryogen or other harmful material to leak into the body. Moreover, the heating with RF energy inherently causes an increase in the temperature of the fluid in the balloon which would yield higher pressures. Applicant's specification is completely void of any disclosure of the pressures associated with an RF embodiment and claim 10 is therefore not supported in the originally filed specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Joye et al (6,428,534).

Joye et al disclose a catheter device that is inflated and deflated within the cardiovascular system for performing cryogenic angioplasty. In particular, Joye et al disclose that it is advantageous to use lower balloon pressures (e.g. 2 bar, col. 8, lines 5-7) for ablating tissue with cryogenic cooling. In particular, Joye et al disclose various balloon inflation pressures and cycles, including flushing the balloon with a saline and dry gas (i.e. very low pressure), then pressurizing with a cryogen to treat the area (col. 9, lines 25-31). The pressure during the cryogen cycle, while still low, would be greater than the pressure in the balloon during the flushing cycle which is performed merely to remove fluids and debris before introducing the pressurized cryogen. Joye et al also disclose a pressure control feedback mechanism (col. 8, lines 5-20) which includes a control means on a console for controlling the necessary valves to regulate the delivery of cryogen from the cryogen source.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Edwards (6,258,087).

The Joye et al device and method of use has been addressed previously. While Joye et al disclose a controller to control the fluid delivery to maintain a desired pressure in the balloon, there is no specific teaching of using a PID controller. The examiner maintains that the use of PID controllers is generally known in the art, and Edwards fairly teaches the use of such a controller to control fluid flow (col. 36, lines 15-20).

To have provided the Joye et al system with a PID controller to control the fluid flow based on sensed conditions such as pressure would have been an obvious consideration for one of ordinary skill in the art since Edwards teaches the use of such a control mechanism to control fluid delivery.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Stern (5,443,470).

Joye et al disclose cryoablation as addressed previously, but fail to teach the alternative (or additional) use of RF energy.

Stern, as addressed in the previous Office action, disclose a balloon ablation apparatus that uses either RF energy or cryogenic energy to effect ablation of tissues with the balloon device.

Hence, to have provided the Joye et al system with an RF treatment means for ablating tissue would have been an obvious modification for one of ordinary skill in the art since Stern fairly teaches that it is known to use either RF energy or cryogenic energy to affect ablation of tissue with a balloon device.

Claims 3, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Joye et al (2002/0045894).

Joye et al disclose a system including a controller for controlling the inflation and deflation of the balloon, including controlling the pressure within the balloon. There is no express depiction of a control console for performing this manipulation. The examiner maintains that as is generally known in all such systems, a control panel is present to afford the user access to control buttons. However, in order to more clearly show that such a control panel is known, attention is directed to the Joye et al ('894) references which specifically shows a control console (78) used for inflating and deflating a balloon (22). Joye et al further specifically teach of the use of a proportional valve (68) for maintaining a pressure in the balloon, as well as the use of a fixed volume reservoir (72) coupled to the proportional valve (68).

To have provided the Joye et al with a control console, proportional valve and a fixed volume reservoir to controlling the inflation/deflation and the pressure within a balloon structure would have been an obvious modification for one of ordinary skill in the art since Joye et al ('894) teach the use of such components in an analogous system for the same purpose.

Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller (3,924,628) in view of the teaching of Joye et al ('534).

The Droegemueller device has been addressed previously. Droegemueller disclose the use of the device to treat uterine tissue, but specifically state that the device may be used in other treatment areas (col. 8, lines 5-10) with modification of the balloon shape/size. The examiner maintains that use of the device to treat blood vessels would be an obvious consideration since Joye et al fairly teach that it is known to use cryo-balloon devices to treat blood vessels. Joye et al also specifically teach that it is known to use lower balloon pressures (e.g. about 2 bar) when using a cryo-balloon device, and Droegemueller also disclose the use of low balloon pressures. Joye et al further disclose the particular controller and sensors used to deliver fluids to the balloon member and to control the inflation pressure in the balloon.

To have used the Droegemueller balloon device to ablate tissue in the cardiovascular system would have been an obvious consideration for one of ordinary skill in the art, particularly since Droegemueller specifically disclose the device may be used in areas other than uterine tissue, and further since Joye et al teach that it is known to use cryo-ablation balloons having low inflation pressures to treat cardiovascular tissues.

Claims 4, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) and Joye et al ('534) and further in view of the teaching of Edwards (6,258,087).

The combination of the Joye et al teaching with the Droegemueller devices has been addressed previously. While Joye et al disclose a controller to control the fluid

delivery to maintain a desired pressure in the balloon, there is no specific teaching of using a PID controller. The examiner maintains that the use of PID controllers is generally known in the art, and Edwards fairly teaches the use of such a controller to control fluid flow (col. 36, lines 15-20).

To have provided the Droegemueller device, as modified by the teaching of Joye et al, with a PID controller to control the fluid flow based on sensed conditions such as pressure would have been an obvious consideration for one of ordinary skill in the art since Edwards teaches the use of such a control mechanism to control fluid delivery.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Droegeumuller ('628) and Joye et al ('534) in view of the teaching of Stern (5,443,470).

Droegemueller and Joye et al disclose cryoablation as addressed previously, but fail to teach the alternative (or additional) use of RF energy.

Stern, as addressed in the previous Office action, disclose a balloon ablation apparatus that uses either RF energy or cryogenic energy to effect ablation of tissues with the balloon device.

Hence, to have provided the Droegemueller device, as modified by the Joye et al system, with an RF treatment means for ablating tissue would have been an obvious modification for one of ordinary skill in the art since Stern fairly teaches that it is known to use either RF energy or cryogenic energy to affect ablation of tissue with a balloon device.

Claims 3, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller (‘628) and Joye et al ('534) and further in view of the teaching of Joye et al (2002/0045894).

Joye et al disclose a system including a controller for controlling the inflation and deflation of the balloon, including controlling the pressure within the balloon. There is no express depiction of a control console for performing this manipulation. The examiner maintains that as is generally known in all such systems, a control panel is present to afford the user access to control buttons. However, in order to more clearly show that such a control panel is known, attention is directed to the Joye et al (‘894) references which specifically shows a control console (78) used for inflating and deflating a balloon (22). Joye et al further specifically teach of the use of a proportional valve (68) for maintaining a pressure in the balloon, as well as the use of a fixed volume reservoir (72) coupled to the proportional valve (68).

To have provided the Droegemueller system, as modified by the teaching of the Joye et al, with a control console, proportional valve and a fixed volume reservoir to controlling the inflation/deflation and the pressure within a balloon structure would have been an obvious modification for one of ordinary skill in the art since Joye et al (‘894) teach the use of such components in an analogous system for the same purpose.

Response to Arguments

Applicant's arguments filed May 8, 2007 (and entered as part of the June 28, 2007 RCE) have been fully considered but they are not persuasive.

Regarding the 35 USC 112, first paragraph issues, the examiner maintains there is no explicit teaching of inflating an expandable membrane to a predetermined target pressure, then ablating tissue wherein pressure exceeds the target pressure. Also, there is no disclosure of a target pressure that is 5-20 psi. The paragraphs cited in support of the use of a "predetermined target pressure" merely state that the balloon is inflated in order to provide sufficient mechanical force for ablation. There is no disclosure that the balloon is inflated to a “predetermined target pressure”. The range of pressure necessary to inflate a balloon would vary greatly, and there is no indication that there is a target pressure (e.g. 1psig) associated with the inflation of the balloon. Also, the disclosure of a pressure switch being used to regulate pressure after inflation is not an express disclosure of providing a pressure greater than the target pressure during ablation. Rather, the pressure regulator merely implies the pressure may be increased or decreased as desired. There is simply no express disclosure of the steps for controlling the pressure in the expandable member in the manner required by the language of claims 1 and 11. And regarding the specific pressure range (i.e. 5-20 psi), applicant can not simply select a preferred target range based on a broadly disclosed range and claim support exists for the narrower range. This would be like applicant disclosing and claiming an element being made of metal, and then later amending the claims to recite the element is made of titanium with no supporting disclosure in the specification of that specific material. If the preferred pressure range was 5-20 psi, and that range was critical to the function of the balloon member, then that range should have been expressly disclosed in the originally filed specification. As originally filed,

applicant only provides support for a working pressure that is "preferably lower than 20 psia" (paragraph 0054).

Regarding the prior art rejections, new grounds of rejection have been made based on applicant's amendments to the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
January 21, 2009